REMARKS

Claims 1-4, 7, 8, 11, 14, 17, 20-22, 27, 34, and 36 (and presumably claim 5) are pending. Claims 9, 10, 12, 13, 15, 16, 18, 19, 23 to 26, 28-33, 35, and 37-40 are currently canceled. Claim 6 has been withdrawn from consideration. Claims 1 and 27 are currently amended. Reconsideration of the application is requested.

Claims 1 and 27 have been amended to further clarify that surface removal of "a substantial amount" of the IRM means removal of "at least 50% of the IRM that was originally applied," as supported by page 5, lines 7-9 of the present specification.

§ 103 Rejections

Claims 1-4, 7, 8, 11, 14, 17, 20-22, 27, 34, and 36 (and presumably claim 5) are rejected under 35 USC § 103(a) as being unpatentable over Hedenstrom (2002/0058674) in view of Mitra *et al.* (WO/2002/102477) in further view of Gordon *et al.* (20040014779). Applicants respectfully disagree because removing at least 50% of the IRM that was applied would not have been obvious to one skilled in the art at the time the claimed invention was made. Although, the '674 patent teaches the application of IRMs to mucosal surfaces, it does not teach or suggest the claimed invention of removing at least 50% of the IRM compound that was applied before it would be naturally absorbed or eliminated. This is a counterintuitive approach that is not at all suggested in the cited references.

Indeed, '674 teaches away from the claimed invention because it stresses the importance of complete delivery (¶ 0070) and increased residence time of IRMs on mucosal surfaces (see, e.g., ¶ 0327).

Although '674 teaches the use of the same types of devices to apply the IRM, the method of using the devices is different – and the methods of the claimed invention are not taught or suggested by the use of the devices in the '674 patent. For example, '674 teaches the use of a cervical cap to topically apply an IRM to the cervical mucosa (¶ 0344). However, '674 suggest formulating the IRM to include a viscosity agent "to enhance the residency time of the IRM on the cervix." Indeed, the preferred viscosity enhancing agent of '674 has "mucoadhesive properties" (¶ 0327), impeding its removal. Although a cervical cap may also be used to practice the claimed invention (page 16, line 20), the intent is not to increase residency time on the

surface but rather to deliver a formulation such that the IRM "can be removed by withdrawing the device from contact with the mucosal surface" (page 16, lines 21-22). Similarly, US 6328991 also teaches the use of a vaginal sponge for drug delivery, but it does not suggest the sponge should be removed before the drug could be naturally absorbed. Rather, it notes "the sponge may be maintained within the vagina for prolonged periods of time while continuing to provide release of the active agent from the reservoir" (column 7, lines 44-46). Indeed, the "invention contemplates… the drug will be released on a sustained basis over a relatively long period of time" (column 8, lines 60-63). In contrast, the claimed invention contemplates using these devices to provide a short, substantial dose of IRM to "kick-start" the immune system, with at least 50% of the IRM that was applied then being removed before it can cause the irritation and side effects that a sustained release over a long period of time would produce.

The Office Action contests that "one skilled in the art would have known that the device could be removed after insertion within a certain period of time and the substantial amount of the drug applied to the device, which is not absorbed to the mucosal surface, would be removed along with the device" (page 9). However, there is nothing in any of the cited art to suggest that the device should be removed before the drug had been absorbed to the mucosal surface – or that such a removal would result in less irritation while providing an effective therapy (page 3, lines 25-27).

Thus, conjecture that the claimed invention could have been practiced by using the devices of the cited art is not sufficient to establish a *prima facie* showing of obviousness. Nothing in the cited art teaches or suggests the improvements that result from practicing the methods of the claimed invention – indeed, the cited art suggests that removing the IRM before it could be absorbed would be detrimental (¶ 0012).

Furthermore, although the '674 teaches the therapeutic benefits of IRMs may be hindered and new methods and formulation and systems were needed (¶ 0007; Final Office Action, page 4), it suggests that delivery of reduced volumes should be avoided because of the "serious consequences of ineffective treatment" (¶ 0012). The methods of '674 address the need for new systems by localized application of IRMs, but '674 fails to teach or suggest the claimed invention's limitation of removing from the mucosal surface at least 50% of the IRM that was

originally applied at a time before it would otherwise be naturally absorbed or eliminated. Thus, the improvements of the claimed invention over the prior art are not obvious.

The rejection of claims 1 and 27 under 35 USC § 103(a) as being unpatentable over Hedenstrom in view of Mitra *et al.* in further view of Gordon *et al.* has been overcome and should be withdrawn.

Claims 2-5, 7, 8, 11, 14, 17, 20-22, 34, and 36 each add additional features to claim 1 or claim 27. Claims 1 and 27 are patentable for the reasons given above. Thus, claims 2-5, 7, 8, 11, 14, 17, 20-22, 34, and 36 are likewise patentable.

In summary, the rejection of claims 1-4, 7, 8, 11, 14, 17, 20-22, 27, 34, and 36 (and presumably claim 5) under 35 USC § 103(a) as being unpatentable has been overcome and should be withdrawn.

In view of the above, it is submitted that the application is in condition for allowance. Examination and reconsideration of the application as amended is requested.

Respectfully submitted,

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